



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,739	11/20/2001	Kazuo Shinozaki	10235/10	8960
23838 7590 12/28/2007 KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			EXAMINER KUMAR, VINOD	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 12/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/988,739

Applicant(s)

SHINOZAKI ET AL.

Examiner

Vinod Kumar

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-9,12 and 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,10,11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :02/12/02, 10/07/02, 5/20/03, 10/23/06, 1/25/07.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II (claims 2, 10, 11 and 13) and a promoter of SEQ ID NO: 13 in the reply filed on September 21, 2007 is acknowledged. However, it is noted that Applicant did not provide any arguments for their traversal.

Claims 1, 3-9, 12, 14-17 and SEQ ID NOs: 1-12, and 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed (without any arguments) the restriction (election) requirement in the reply filed on September 21, 2007.

Accordingly, claims 2, 10-11, and 13 in conjunction with the elected promoter sequence of SEQ ID NO: 13 are examined on merits in this Office action. This restriction is made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

2. Initialed and dated copies of Applicant's IDS form 1449 filed February 12, 2002,

Art Unit: 1638

October 7, 2002, May 20, 2003 (abstract only, no English translation provided), October 23, 2006, and January 25, 2007 are attached to the instant Office action. The submission are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Priority

3. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copies of Application No. Japan 356652/2000, filed on November 22, 2000, and Japan 309984/2001, filed on 10/05/2001 have been received.

Specification

4. The abstract of the disclosure is objected to because it is not limited to a single paragraph. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. See MPEP § 608.01(b).

Appropriate correction is requested.

Claim Objections

5. Claim 2 is objected to because of the following informalities:

Claim 2 is objected for having non-elected SEQ ID NOs.

Appropriate action is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 10, 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "stringent conditions", in line 9, part (c), which is confusing since it is unclear what level of stringency is encompassed by "stringent conditions". Page 15 (lines 4-7 of 4th paragraph) of specification gave examples but did not define "stringent conditions". The recitations "preferably" in line 5, and "more specifically" in line 6 of page 15 (4th paragraph) of the specification makes it unclear for one skilled in the art to determine whether the recitation "stringent conditions" in the claim encompasses high, medium or low stringent conditions of hybridization. One of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Dependent claims 10, 11, and 13 are also rejected because they fail to overcome the deficiency of claim 2.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Art Unit: 1638

7. Claims 2 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter.

Claims 2 and 10 read on a naturally occurring environmental stress responsive promoter per se. The environmental stress responsive promoter, as claimed in claims 2 and 10 have the same characteristics as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that claim 2 be amended by inserting the term --isolated-- before "environmental" and after "An" in line 1, to identify a product that is not found in nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2, 10, 11, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an abiotic (e.g. cold, drought or high salt) environmental stress responsive promoter of SEQ ID NO: 13, does not reasonably provide enablement for (a) a nucleotide sequence comprising one or more deletions, substitutions or additions in the nucleotide sequence of SEQ ID NO: 13, (b) a DNA

Art Unit: 1638

hybridizing under stringent conditions to the nucleotide sequence of SEQ ID NO: 13, and (c) biotic (e.g. pathogen, insect etc.) environmental stress responsive promoter activity of SEQ ID NO: 13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims are broadly drawn to an environmental stress responsive promoter comprising a DNA consisting of one or more deletions, substitutions or additions in the promoter sequence of SEQ ID NO: 13, or a DNA which hybridizes under stringent conditions to SEQ ID NO: 13.

Claim 2 is directed to a DNA consisting of a nucleotide sequence comprising one or more deletions, substitutions, or additions in the promoter sequence of SEQ ID NO: 13.

The instant specification, however, only provides guidance for how to make and use a nucleic acid sequence of SEQ ID NO: 13 which is isolated from *Arabidopsis*. The specification teaches cold, drought and high salt inducible promoter activity of SEQ ID NO: 13 which is operably linked to FL05-18-112 gene coding sequence. The specification teaches using Microarray based assay in determining abiotic stress-inducible promoter activity of SEQ ID NO: 13. See page 39, Figures 27-29.

The specification, page 14, 2nd paragraph, lines 1-5, says:

The promoter of the present invention comprises a nucleotide sequence comprising deletions, substitutions or additions of one or more nucleotides, relative to the nucleotide sequence of SEQ ID NO: 13.

Art Unit: 1638

The specification does not provide guidance in the specification with respect to making nucleotide changes in SEQ ID NO: 13.

Thus, from the guidance in the specification, it would appear that the vast majority of the nucleotides in SEQ ID NO: 13 could be substituted with any other nucleotide.

Making nucleotide change(s) in a nucleotide sequence which is capable of initiating transcription in a plant cell is highly unpredictable. While it is known that many nucleotide substitutions, additions or deletions are generally possible in any given nucleic acid sequence (promoter) capable of initiating transcription in a plant cell, the positions within the promoter sequence where such nucleotide changes can be made with a reasonable expectation of success (without abrogating specific promoter activity) are limited.

It was well established in the art at the time the claimed invention was made that changing a single base randomly would abrogate promoter activity. See, for example Kim et al. (Plant Molecular Biology, 24:105-117, 1994) who teach that small alterations in a nos (nopaline synthase) promoter strongly influenced promoter strength. See in particular, page 108, table 1; page 109, table 2.

Neither the state of art at the time the invention was made nor Applicant provided guidance as to which region(s) of SEQ ID NO: 13 should be conserved and which region(s) would tolerate addition, deletion, substitution of one or more nucleotides without abrogating the promoter activity. The specification fails to provide guidance as to which region(s) of SEQ ID NO: 13 should be conserved and which region(s) would

Art Unit: 1638

tolerate additions, deletions, and/or substitutions of one or more nucleotides without abrogating the environmental stress responsive promoter activity when used to express a desired coding sequence of interest in a plant.

Neither the state of art nor Applicant provided guidance as to how inoperable embodiments could have been readily eliminated other than random trial and error. In the absence of guidance, making and analyzing nucleic acid sequences with a large number of nucleotide changes that have environmental stress-responsive promoter activity would require undue experimentation. It would also have been highly unpredictable for one skilled in the art to determine how to use variants of SEQ ID NO: 13 for initiating transcription in an environmental stress responsive manner in a plant. Promoters, unlike proteins, do not have conservative base or amino acid substitutions. A single nucleotide difference, can abrogate promoter activity, as indicated above (Kim et al.).

In the absence of guidance, making and analyzing DNA sequences with a large number of nucleotide changes that have the ability to initiate transcription in an environmental stress-responsive manner in a plant would require undue experimentation.

Mutation of promoter sequences also produces unpredictable results. For example, Donald et al. (EMBO J. 9:1717-1726, 1990,) in a mutational analysis of the *Arabidopsis rbcS-1A* promoter found that the effect of a particular mutation was dependent on promoter fragment length (paragraph spanning pg 1723-1724).

Art Unit: 1638

The region of a given promoter that has a specific activity cannot be predicted and involves the complex interaction of different subdomains (see Benfey et al., Science 250:959-966, 1990; see Abstract, Fig. 3-5). Even a very small region may be critical for activity, and the criticality of a particular region must be determined empirically (see Kim et al., Plant Mol. Biol. 24:105-117, 1994; Tables 1-4, Abstract, Fig. 1-2).

Thus, extensive teachings are required for making DNA comprising a nucleotide sequence having unspecified changes in the nucleotide sequence of SEQ ID NO: 13 that has environmental stress responsive activity. In the absence of guidance, undue experimentation would have been required at the time the claimed invention was made to determine which sequences are needed in the instantly claimed promoter that are required for an environmental stress responsive activity. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claim 2 is directed to a DNA hybridizing under stringent conditions to an environmental stress-responsive promoter having the nucleotide sequence of SEQ ID NO: 13. The specification (pg 15, lines 4-7 of 4th paragraph) provides examples of stringent conditions which would encompass hybridization of nucleotide sequence(s) that are unrelated to SEQ ID NO: 13. This implies that a nucleic acid sequence lacking an environmental stress responsive promoter activity would also hybridize to SEQ ID NO: 13 under said stringent conditions of hybridization.

It may be emphasized that it was very well established in the art (Maniatis et al., Molecular Cloning: A Laboratory Manual, Cold Spring Harbor Laboratory (1982), see in particular, pages 387-389) at the time the claimed invention was made that in order to prevent hybridization of unrelated nucleotide sequence(s) to a target sequence, hybridization and subsequent washing conditions must be highly stringent. For example, hybridization under conditions of 0.1-1.0x SSC, 50% formamide and 50 °C for 24 hours, followed by 2 washes in 0.1% SDS, 0.1x SSC at 65 °C for 25-30 minutes each is considered highly stringent condition that would not allow hybridization of unrelated nucleotide sequences to the target sequence.

In the absence of guidance, undue experimentation would have been required by a skilled artisan at the time the claimed invention was made to determine, how to use an unrelated nucleotide sequence that would hybridize to SEQ ID NO: 13 under stringent conditions encompassed by the instantly claimed invention. The specification does not provide guidance on how to use said unrelated DNA (nucleotide sequence) in obtaining environmental stress-responsive promoter activity. In the absence of guidance, undue experimentation would have been required by one skilled in the art at the time the claimed invention was made to determine how to use said unrelated DNA in driving the expression of a nucleic acid sequence of interest in an environmental stress responsive manner.

Claim 2 is directed to *any* environmental stress-responsive promoter activity of SEQ ID NO: 13. The breadth of the phrase "environmental stress" encompasses abiotic (e.g. cold, drought, high salt etc.) and biotic (pathogens, insect etc.) type of stresses.

Art Unit: 1638

Specification provides guidance on high salt, low temperature and dehydration (abiotic) stress responsive activity of SEQ ID NO: 13. Specification does not provide guidance on biotic stress-responsive activity of SEQ ID NO: 13 as encompassed by the breadth of the claim.

The state of art teaches existence of different stress-responsive transcriptional regulatory elements within plant genome, and the stress-responsive transcriptional regulatory elements are stress-specific. The state of art also suggests that plant stress-responsive promoters comprise stress-specific *cis*-regulatory elements, which participate in regulating promoter activity in a stress-specific manner through their binding with stress-specific transcriptional factor(s). See for example, Yamaguchi-Shinozaki et al. (Trends in Plant Science, 10:88-94, 2005; see in particular, page 88, abstract; page 89, 2nd column; page 90, figure 2, table 1).

The state of art also teaches existence of a complex cross-talk among different types of stress responses in plants. See for example, Logemann et al. (PNAS, 99:2428-2432, 2002) who teach that pathogen response element contains one or multiple copies of the TGAC or W-box core sequence which is specifically regulated by WRKY transcriptional factor family, whereas, UV-responsive genes (abiotic stress responsive, emphasis added) are activated through a light-regulatory promoter unit comprising one basic leucine zipper (bZIP)-binding, ACGT containing element (ACE) and one MYB-recognition element (MRE). The reference teaches that pathogen (biotic stress) defense overrides UV protection (abiotic stress) by selective transcriptional

Art Unit: 1638

down-regulation of one or a few metabolic pathways. See in particular, page 2428, abstract; page 2431, 2nd column).

The specification does not provide guidance on *cis*- regulatory elements of SEQ ID NO: 13 that may respond to a biotic type of environmental stress condition. The specification does not provide guidance on *cis*- regulatory elements of SEQ ID NO: 13 that may respond to abiotic and biotic type of environmental stress conditions. In the absence of adequate guidance, undue experimentation would have been required by a skilled artisan at the time claimed invention was made to determine how to use SEQ ID NO: 13 for the full scope of environmental stress responsive promoter activity.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would have been required by one skilled in the art to make and use the claimed invention commensurate in scope with the teachings of the specification.

9. Claims 2, 10, 11, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to an environmental stress responsive promoter comprising a DNA consisting of one or more deletions, substitutions or additions in the promoter sequence of SEQ ID NO: 13, or a DNA which hybridizes under stringent conditions to SEQ ID NO: 13.

Art Unit: 1638

The essential feature of the claim 2 is a DNA consisting of a nucleotide sequence having one or more deletions, substitutions or additions of nucleotides as compared to the environmental stress responsive promoter of SEQ ID NO: 13.

The specification describes the function of cold, drought and salt stress responsive promoter activity of SEQ ID NO: 13. See page 39, Figures 27-29.

The specification does not describe the structures comprising one or more nucleotide changes compared to SEQ ID NO: 13. The specification does not describe the function of an environmental stress responsive promoter activity for said structures.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of a stress-responsive promoter activity or transcriptional activity of SEQ ID NO: 13.

The only species described in the specification is SEQ ID NO: 13. Nucleotide sequences having unspecified deletions, additions and/or additions of nucleotides compared to SEQ ID NO: 13 are not described in the specification and thus their function is unknown.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 13 is insufficient to describe the claimed genus.

Art Unit: 1638

The essential feature of claim 2 is a nucleotide sequence which hybridizes to SEQ ID NO: 13 under stringent hybridization conditions and which exhibits environmental stress responsive promoter activity of SEQ ID NO: 13.

The specification describes the function of cold, drought and salt stress responsive promoter activity of SEQ ID NO: 13. See page 39, Figures 27-29.

The specification fails to describe the structure of nucleotide sequence(s) that would hybridize with SEQ ID NO: 13 under the conditions recited in the claim. The specification (pg 15, lines 4-7 of 4th paragraph) provided examples of stringent conditions which would encompass hybridization of nucleotide sequence(s) that are unrelated to SEQ ID NO: 13. The specification fails to describe the function of environmental stress responsive promoter activity for said hybridizing structures (sequences).

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of SEQ ID NO: 13 that is required for an environmental stress responsive promoter activity.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 13 is insufficient to describe the claimed genus.

Hence, Applicant has not, in fact, described the following: (a) nucleotide sequences having one or more nucleotide deletions, additions and/or substitutions

Art Unit: 1638

compared to SEQ ID NO: 13, and (b) nucleotide sequences that hybridize to SEQ ID NO: 13 under the stringent conditions, and the specification fails to provide written description of the claimed genus.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed composition, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 2, 10-11 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Mine et al. (US Patent No. 6,084,089, Issued July 4, 2000).

Claims are drawn to an environmental stress responsive promoter comprising (a) DNA consisting the nucleotide sequence of SEQ ID NO: 13, (b) DNA consisting of a nucleotide sequence comprising of one or more deletions, substitutions or additions in the promoter sequence of SEQ ID NO: 13, or (c) a DNA which hybridizes under stringent conditions to SEQ ID NO: 13, or an expression vector comprising said

Art Unit: 1638

promoter, or wherein said stress is cold, drought, salt or photo stress, or wherein said vector further comprises a desired gene.

Mine et al. disclose cold-inducible (same as cold responsive) promoters (SEQ ID NOs: 1 and 2) isolated from potato. The reference also discloses an expression vector comprising said cold-inducible promoter operably linked with a coding sequence of luciferase gene (a desired gene). The reference also discloses cold responsive promoter activity of said promoters (SEQ ID NO: 1, SEQ ID NO: 2) by transforming a plant with said expression vector. The reference further discloses that the promoter sequence of SEQ ID NO: 1 or SEQ ID NO: 2 hybridizes to a nucleotide sequence under stringent conditions of hybridization. See in particular, abstract, column 10, example 5; column 12, example 8; columns 13-14, tables 7 and 8; SEQ ID NOs: 1 and 2.

This rejection has been made because of following reasons:

a) Part (b) of claim 2 also reads on any environmental stress inducible promoter because of unspecified substitutions, deletions and/or additions in the nucleotide sequence of SEQ ID NO: 13.

b) The stringent conditions recited in part (c) of claim 2 also reads on any DNA with an environment stress responsive activity that would hybridize to instant SEQ ID NO: 13 under said conditions of hybridization. The specification (pg 15, lines 4-7 of 4th paragraph) provided examples of stringent conditions which would also encompass hybridization of nucleotide sequence(s) having poor homology to SEQ ID NO: 13 but exhibiting an environmental stress-responsive activity.

Thus, Mine et al. anticipated the claimed invention.

Art Unit: 1638

11. Claims 2, 10-11 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Rounsley et al. (NCBI, GenBank, Sequence Accession No. AC005309, Published October 13, 1998).

Claims are drawn to an environmental stress responsive promoter comprising (a) DNA consisting the nucleotide sequence of SEQ ID NO: 13, (b) DNA consisting of a nucleotide sequence comprising of one or more deletions, substitutions or additions in the promoter sequence of SEQ ID NO: 13, or (c) a DNA which hybridizes under stringent conditions to SEQ ID NO: 13, or an expression vector comprising said promoter, or wherein said stress is cold, drought, salt or photo stress, or wherein said vector further comprises a desired gene.

Rounsley et al. disclose an expression vector comprising a nucleotide sequence which has 100% sequence identity to instant SEQ ID NO: 13. See sequence positions 34137 through 36136. The reference also discloses that the nucleotide sequence disclosed in the reference is operably linked with a nucleic acid sequence encoding a stress-related protein. The reference further discloses additional genes present in said vector. See in particular, pages 1, 7-8, and 27-28. It may be emphasized that BAC clone disclosed in the reference is also an expression vector present in a host cell, such as bacteria. The vector disclosed in the reference comprises all the structural elements of the instantly claimed expression vector.

The property of an environmental stress (e.g. cold, drought, salt) responsive promoter activity is inherent to the nucleotide sequence disclosed in the reference. The

Art Unit: 1638

property of hybridizing to a DNA under stringent conditions is also inherent to the nucleotide sequence disclosed in the reference.

Accordingly, Rounsley et al. anticipated the claimed invention.

Conclusions


12. Claims 2, 10-11, and 13 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Vinod Kumar
Patent Examiner
Art Unit 1638